

Pharmacovigilance in the 21st Century Big Challenges, Big Opportunities.....

Ushma Mehta

Centre for Infectious Disease Epidemiology and Research (CIDER)

University of Cape Town



Declarations:

- The speaker's salary and UBOMI BUHLE project is funded by the US CDC and the Bill and Melinda Gates Foundation
- The views expressed in this presentation are my own and do not necessarily reflect the views or positions of my employer or funder.
- The images in this presentation are copied as "fair use".

Medicine in the 21st Century

| | |
|----------------------|---|
| Predictive | <ul style="list-style-type: none">• Improve linkages from preclinical to post-marketing across products• Pharmacogenomics• Improved data science to harness value of large data sets |
| Preventive | <ul style="list-style-type: none">• Electronic medical records – drug-drug, drug-disease interaction tracking• Improved measurement of performance (both safety and efficacy) of medicines in the market- linking exposures to outcomes – linking this data to clinical practice and payment• Proactive PV with risk management plans• Smarter ADR reporting (EMR with suspicion of ADR) |
| Personalised | <ul style="list-style-type: none">• Pharmacogenomics• Improved record linkage systems across geographies – continuity of care – longer term monitoring and signal detection• Electronic alerts aimed at reducing medication errors• Targeted advertising of products |
| Participatory | <ul style="list-style-type: none">• Regulatory decision-making more participatory – engaging public and health professionals• Proactive stakeholders – industry, lobby groups, media, health professions• Improved access to product information and accountability |

Adapted and inspired by Arlett et al Clin Pharm and Therapeutics – Jan 2020



5 key messages of this talk

- No news is not necessarily good news...
- Medicines...I mean Opiates are the religion of the people
- Pure water is pure medicine.....
- Data data everywhere....but not a thought to think
- Its not how much you know or even what you prescribe.....

No News is
not
necessarily
good news



Some factors affecting our ability to detect safety signals

Evolving **diagnostic technology** and access

e.g. Fen-Phen (improved cardiac ultrasound)

Evolving Data science and epidemiology – population-based record linkage health information systems facilitate large-scale studies, longer follow-up and in-built control groups at minimal cost

e.g. Proportion of women in exposed to potential teratogens during first

Collaborations between scientific disciplines, harmonization initiatives and data pooling

e.g. Valproate and neurodevelopmental problems in infants exposed in utero (>30 years after licensing!)

Expanded indications, and other changes in access

e.g. OTC availability of gastric acid inhibitors and potential increased risk of

adverse renal events, gastric cancer, dementia, food allergy, bacterial overgrowth, decreased bone health dental implant survival.....

Political awareness and will, allocated resources and vested interests

Are Vaccines Licensed in HIC really *less* safe than those almost exclusively licensed in LMIC? (as at 6 May 2022)

| COVID-19 Vaccine | HIC (ICH) where vaccine licensed | Signals (EU website, WHO GACVS website, UMC Signals) |
|-----------------------------------|---|---|
| Moderna vaccine | UK, USA, EU, Australia, Japan, Canada, Israel | Myocarditis /pericarditis, capillary leak syndrome flare-up, ? Myocardial infarction, pulmonary embolism and thromboses, menstrual irregularities, paraesthesia, tinnitus, hearing loss |
| Oxford AstraZeneca vaccines | UK, EU, Australia, Japan, Canada | Anaphylaxis & severe allergy, TTS, GBS, transverse myelitis, immune thrombocytopenia, tinnitus, hearing loss |
| Pfizer/BioNTech vaccine | UK, USA, EU, Australia, Japan, Canada, Israel | Myocarditis/pericarditis, menstrual irregularities, tinnitus, hearing loss |
| Janssen (but not available in UK) | UK, USA, EU, Australia, Canada | TTS, cutaneous small-vessel vasculitis, ? Myocardial infarction, transverse myelitis, tinnitus, hearing loss |
| Novavax (but not available in UK) | UK, EU, Australia, Japan, Canada | |
| SII Covishield | | |
| Sinopharm | | |
| Sinovac | | |
| Bharat Biotech | | |
| Nuvaxoid | | |
| Sputnik | | |
| Medicago Covifenz | Canada | |

The Absence of
evidence is not
Evidence of Absence!

Opiates are the religion of the people....

A pill for every current (and possible future) ill

Global medicine spending will increase at a rate of 3-6% per year over the next 3 years. (IQVIA report, 2021)

Medication use is ubiquitous especially self-medication: 2019: 1.8 trillion days of therapy, >200 per person (IQVIA report, 2021)

Focus on opioid crisis in SA:

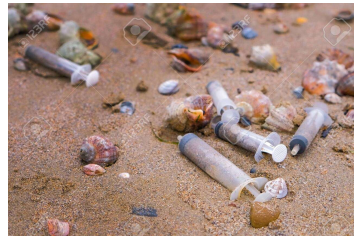
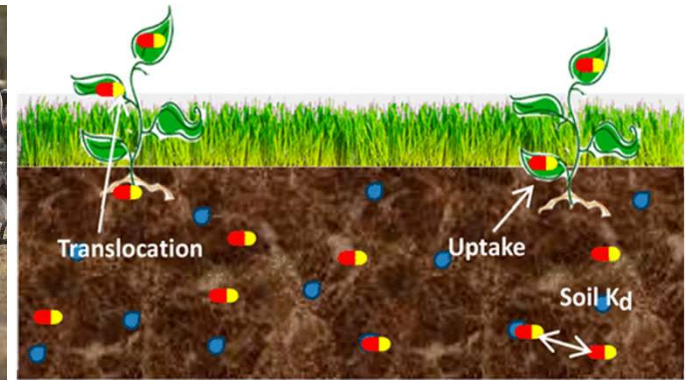
SA sold more OTC opiates (36 dosage units per person) than any other country with available data (Richards et al, 2022)

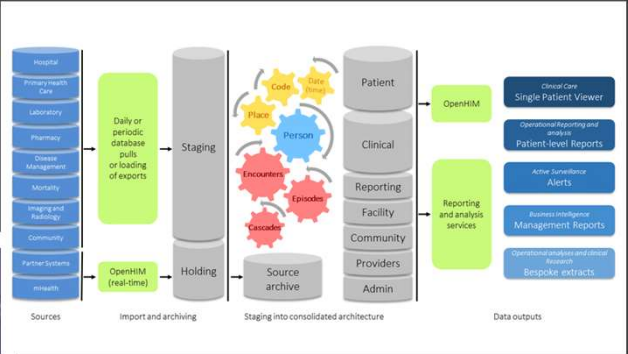
Estimated 8.4% of medical ward admissions in SA are due to ADRs (Mouton JP, 2016)



Pure Water is Pure Medicine

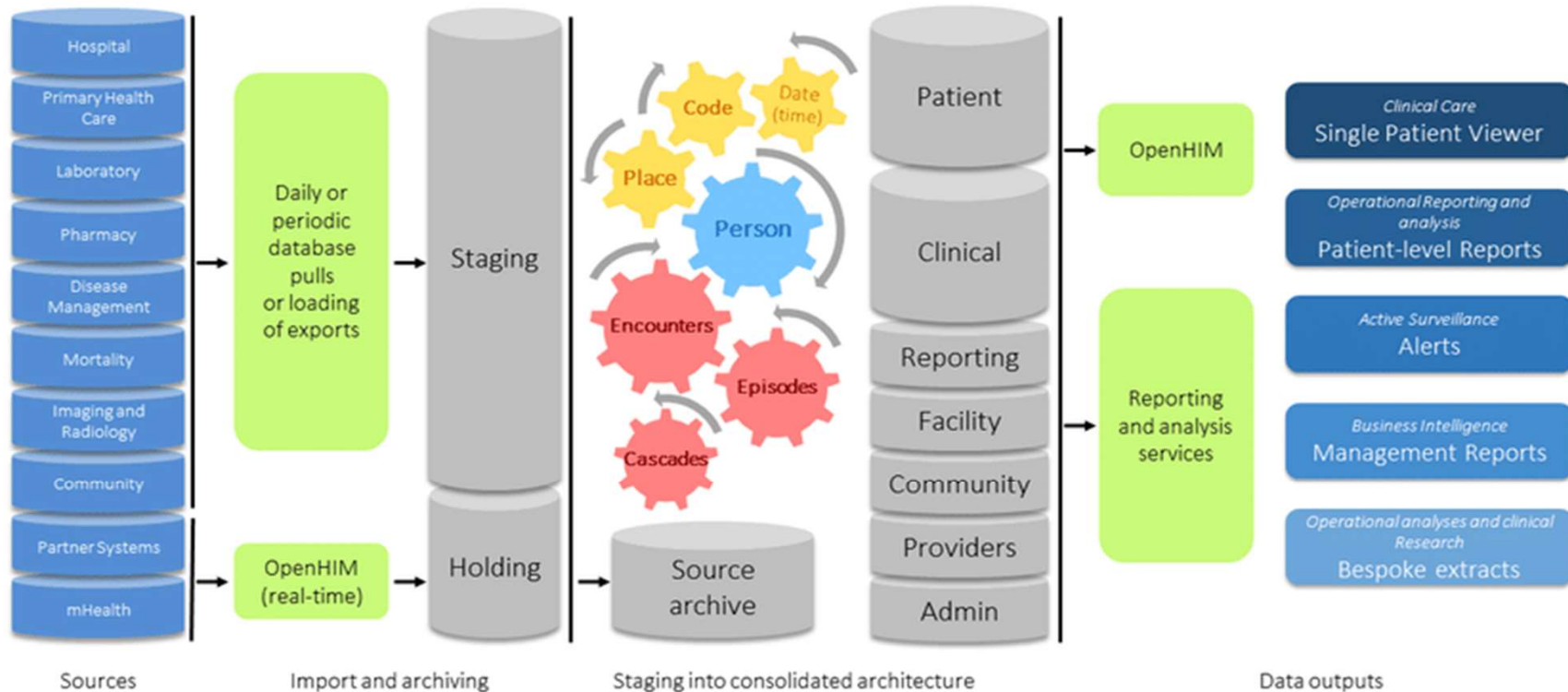
Our
environment is
infused with
medicines and
their packaging





Big Data.....beyond the buzzword...

The Provincial Health Data Centre in the Western Cape – the power of the unique patient identifier!



Social Media and Communication

Consent for follow-up
SMS Messaging expected side effects etc.



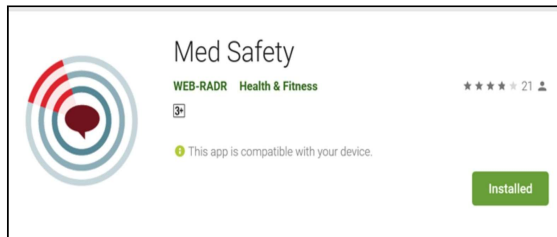
Social Media
listen,engage, broadcast



Telemedicine:
Remote diagnosis and coding

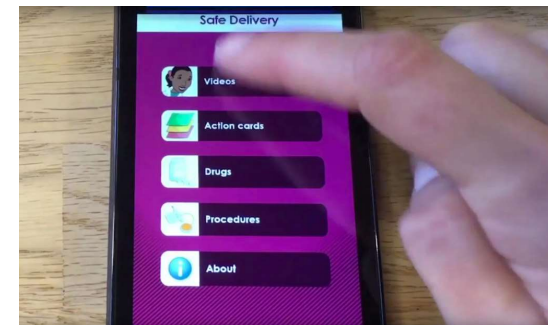


<https://globalbirthdefects.tghn.org/download-birth-defects-surveillance-app>



Reporting AEFIs, ADRs, Pregnancy exposures

Resources and
training for
health professionals



Concluding questions

How do we strike a balance between rational use of genuinely “life-supporting” treatments while addressing overuse of medicines and their devastating impact on human health, animal health and the environment?

How do we create opportunities and develop critical thinking skills to use the data we are collecting for PV to identify signals, public concerns, misinformation, uncertainties and vested interests?

How do we look more holistically at patient safety and PV within the One Health paradigm - recognising the Interconnectedness between animal, environmental and human health?

How to move beyond vested interests and entrenched perspectives when deciding “what is worth knowing” - improving focus on risk of harm?

How to frame the paradox that health technologies have the potential to heal and harm?

How to move from ACCESS TO MEDICINES...to SAFE, RESPONSIBLE ACCESS - with greater product stewardship, judicious medicine use, increased medication literacy and the use of non-drug measures?

Nurse Thandi encourages us to report side effects...

“People don't care how much you know until they know how much you care”
– Theodore Roosevelt

Gathering information is an important first step but (hopefully) not the only step...

By Lwazi Msipha

Thank you for listening!



References

- Arlett P, et al. Pharmacovigilance 2030: Invited commentary for the January 2020 “Futures” Edition of Clinical Pharmacology and Therapeutics. Clin Pharmacol and Therapeutics 2020; 107(1):89-91.
- IQVIA Institute: Global medicines spending and usage trends: Outlook to 2025. <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025>
- Richards GC, et al. Sales of Over-the-Counter Products Containing Codeine in 31 Countries, 2013–2019: A Retrospective Observational Study. Drug Safety 2022; 45 (237-247)
- Mouton JP, et al. Adverse drug reactions causing admission to medical wards: A Cross-sectional survey at 4 hospitals in South Africa. Medicine 2016; 95(19):e3437.
- Global study finds the extent of pharmaceutical pollution in the world’s rivers. <https://www.lancaster.ac.uk/news/global-study-finds-the-extent-of-pharmaceutical-pollution-in-the-worlds-rivers>